

REMARKS

Claim 2 rejected by the Examiner under 35 USC 112, first paragraph, is interpreted to be claim 13 in view of the fact that claim 2 has been cancelled. In response to this rejection, claim 13 has been amended to change "first" to "final" in the claim at two occasions as suggested by the Examiner.

Claim 12 rejected by the Examiner under 35 USC 103(a) has been cancelled, thus rendering the Examiner's comments with regard thereto moot.

Claim 13 has been amended to more clearly define the present invention as a method of forming bottle useful as a pharmaceutical container and dispenser and more clearly defining said invention as forming a cylindrical squeezable bottle having a thickness of between about 0.5 mm and about 2 mm with a volume of between about 5cc and about 15cc.

Support for this amendment may be found in the original specification on page 4, beginning at line 26 and on page 7 beginning at line 27. Accordingly, no new matter has been added.

With specific reference to claim 13 rejected under 35 USC 103(a), the Examiner has stated that U.S. 2001/0048998 A1 to Forte, et al. teaches adding ultraviolet blocker which the Examiner considers a UV absorber and further teaching that similar polypropylenes may be utilized. The Examiner has conceded that Forte, et al. does not explicitly teach first, second, and third polypropylene

resin pellets with the second pellet contains a set of dyestuff absorbing wavelength less than 320nm and a third pellet containing dyestuff absorbing at greater than about 500nm; forming a premixture between the first and second pellets; and forming a final pellet mixture, with the premixture and the third pellets.

The Examiner stated that these steps "seem" to be obvious variations of Forte, et al.'s teaching and that any combination of the above mentioned polypropylenes can be used to produce the final product.

In addition, the Examiner has stated that "one having ordinary skill in the art may decide to mix different proportions of LDPE, MDPE, and HDPE in order to create a final product with the desired material property." However, the Examiner has provided no support for this assertion.

It has been established that factually unsupported opinions of the Examiner do not provide the factual basis required by the Supreme Court in Graham v. John Deere (148 USPQ 459, 1966) for the determination of obviousness under Section 103 (*In re Wagner and Folkers* 152 USPQ 552, 1967). Wagner and Folkers states that neither can such (Examiner) opinions established a "presumption" of obviousness, and that subjective opinions are of little weight.

The Examiner includes numerous conclusory statements that the specific limitations and the claims would be within obvious to one having ordinary skill in the art the time the invention was made. However, it is respectfully

submitted that the level of skill in the art is not determinative, even if it could be established by the Examiner's unsupported opinion. It is held by the decision in *In re Warner and Warner*, 154 USPQ 173 (CCPA 1967), it is Examiner's duty to provide a factual basis for any rejection under 35 USC 103. The Examiner's opinions in the Office Action do not qualify as facts and, therefore, cannot be properly used to support a claim rejection.

Further, the amended claims define the method in accordance with the present invention as being directed to a cylindrical squeezable bottle having specific thickness enabling the squeezing and volume accommodating ophthalmic pharmaceutical formulations.

The Examiner has stated that one having ordinary skill in the art would know that one or more dyestuff could be added to any one of the three resin pellets in any combination as long as the final outcome, after mixing all these three sets of pellets, produces a desired light barrier characteristic such as the blue tint.

The Examiner in the specific in rejections as to features is not following the rule set down in Graham v. Deere, 148 USPQ 459 (Supreme Court 1966) and Connell, et al. v. Sears Roebuck & Co., 220 USPQ 193 (CAFC 1983) in which it is set forth that the test under 35 USC 103 as whether the claimed invention as a whole in light of all the teachings of references in their entirety would have been obvious to one of ordinary skill in the art at the time the invention was made (emphasis added). That is, a determination of obviousness under 35 USC 103 requires

analysis of the claimed invention as a whole, and focusing on obviousness of substitutions and differences, instead of the invention as a whole, is legally improper way to simplify that determination. The Gillette Company v. S.E. Johnson and Company, Inc., 16 USPQ 2d 1923 (CAFC 1990).

The Examiner's gathering features from Forte, et al. which do not teach the whole of the present invention and is substituting the rationale of one skilled in the art for providing a combination which teaches a method of forming a bottle useful as a pharmaceutical container and dispenser utilizing multiple resin pellets for the formation of a cylindrical squeezable bottle for the containment and dispensing of an ophthalmic pharmaceutical. Therefore, the Applicants respectfully requests the Examiner to withdraw the rejection of claim 13 under 35 USC 103(a) on the basis of the Forte, et al. reference.

Claims 14-16 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Forte, et al. in view of Stier and supported by Cook, et al. and further in view of Arakawa.

The Applicants respectfully resubmit the arguments set forth hereinabove and the fact that obviousness under 35 USC 103 must be determined by the invention as a whole and not specific features or elements which isolatedly correspond to specific elements of the present invention.

In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject

matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectfully requested.

Respectfully submitted,



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